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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,659	11/17/2003	Joel V. Weinstock	27045/2032	5366

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,659	WEINSTOCK ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8 and 17-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 17-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2-27-2009 has been entered.

The amendment filed on 2-27-2009 is acknowledged. Claim 8 has been amended. Claims 1-7 and 9 have been canceled. Claims 8 and 17-23 are pending and currently under examination.

Claim Rejections Withdrawn

The new matter rejection of claims 8 and 17-23 are under 35 U.S.C. 112, first paragraph, based on the claim 18 limitation "and determining the level of regulatory T cell activity, wherein an increase in regulatory T cell activity after said administering is indicative of successful treatment." is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 8, 17-18, 20 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstock et al. (WO 99/33479) is maintained for reasons of record.

Applicant argues:

1. Weinstock et al. discloses the determination of Th1 and Th2 responses by measuring the production of various cytokines and cell surface markers after administering a helminthic parasite preparation in order to show efficacy of treatment whereas the instant invention measure the markers and cytokines of T cells.

2. *Foxp3* is only expressed by regulatory T cells which also express increased amounts of IL-10 and/or TGFβ and a decreased amount of IFNγ.

3. Weinstock et al. do not disclose at the differential expression of individual markers and/or cytokines.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the instant claims require the performance of two active steps. First, the administration of a helminthic preparation and secondly, determining the level of regulatory T cell activity. The specification discloses that activity of regulatory T cells can be determined including IL4, IL-5, TGFβ and IFNγ (see paragraph [0049] for example). Given that Weinstock et al. disclose the determination of Th1 and Th2 responses after treatment with the claimed composition "in order to show efficacy" of their method (see page 21) and said responses were determined by measuring the production of various cytokines and cell surface

markers include IL4, IL-5, TGFβ and IFNγ (see pages 21-25), Weinstock et al. anticipates the instant claims.

With regard to Points 2 and 3, the instant claims are not limited to the measurement of *Foxp3* or the differential expression of cytokines or markers.

As outlined previously, Weinstock et al. disclose methods of treating methods of treating diseases associated with an aberrant/enhanced Th1 response by administering a helminthic parasite preparation. Said diseases include Crohn's disease, ulcerative colitis, rheumatoid arthritis, type 1 diabetes mellitus, lupus erythematosis, Sarcoidosis and multiple sclerosis (see abstract). Consequently, Weinstock et al. anticipate all the limitations of the rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 8 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al. (WO 99/33479) is maintained for reasons of record.

Applicant argues:

1. Weinstock et al. discloses the determination of Th1 and Th2 responses by measuring the production of various cytokines and cell surface markers after administering a helminthic parasite preparation in order to show efficacy of treatment whereas the instant invention measure the markers and cytokines of T cells.
2. Predictability is required in maintaining a legal conclusion of obviousness and the Office action provides no grounds on which one of skill could predictably ascertain that regulatory T cells play a role in the treatment of Th1 or Th2 related diseases.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Points 1 and 2, the instant claims require the performance of two active steps. First, the administration of a helminthic preparation and secondly, determining the level of regulatory T cell activity. The specification discloses that activity of regulatory T cells can be determined by measuring a myriad of cytokine and/or surface cell markers including CD4, IL4, IL-5, TGFβ and IFNγ (see paragraph [0049] for example). Given that Weinstock et al. disclose the determination of Th1 and Th2 responses after treatment with the claimed composition "in order to show efficacy" of their method (see page 21) and said responses were determined by

measuring the production of various cytokines and cell surface markers include IL4, IL-5, TGFβ and IFNγ (see pages 21-25), Weinstock et al. meets the limitations of the instant claims. With regards to the role actually plays in the treatment process merely constitutes a further characterization of a known method.

As outlined previously, Weinstock et al. disclose methods of treating methods of treating diseases associated with an aberrant/enhanced Th1 response by administering a helminthic parasite preparation. Said diseases include Crohn's disease, ulcerative colitis, rheumatoid arthritis, type 1 diabetes mellitus, lupus erythematosis, Sarcoidosis and multiple sclerosis (see abstract). Weinstock et al. further disclose the determination of Th1 and Th2 responses after treatment with the claimed composition "in order to show efficacy" of their method (see page 21). Said responses were determined by measuring the production of various cytokines and cell surface markers (see pages 21-25).

Weinstock et al. differs from the instant invention in that they don't explicitly disclose the regulatory T cell markers recited in claims 19 and 21. However, in view of the KSR decision, since the use of screening of the recited T cell activation markers is well known in the art yielding predictable results, it is obvious for the skilled artisan to use them in the methods of Weinstock et al. for determination of Th1 and Th2 responses after treatment with the claimed composition "in order to show efficacy" of their method (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007])

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
May 18, 2009